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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/869,275	06/04/1997	CARL T. WITTWER	T8616.CIP5	5556

7590 06/10/2003

BARNES & THORNBURG  
11 SOUTH MERIDIAN STREET  
INDIANAPOLIS, IN 46204

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
08/869,275

Applicant(s)  
Wittwer et al.

Examiner  
Ardin Marschel

Art Unit  
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 10, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-35, 55-59, 79-82, 87-92, 118-158, and 160-196 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☒ Claim(s) 194 and 195 is/are allowed.
- 6) ☒ Claim(s) 13-35, 55-59, 79-82, 87-92, 118-158, 160, 163-170, 173-193, and 196 is/are rejected.
- 7) ☒ Claim(s) 161, 162, 171, and 172 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/9/01 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Applicants' arguments, filed 2/10/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### **TITLE**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is acknowledged that applicants have amended the title to recite a system. It, however, is noted that the presence of device claims, such as claims 79 etc., are also present. Therefore, the title still is not clearly indicative of the claimed invention in that it only recites systems whereas both systems and devices are claimed.

#### **VAGUENESS AND INDEFINITENESS**

Claims 173-193 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 173, line 12, the phrase "exciting the to cause" is vague and indefinite in that the word "the" seems to indicate the excitation of something which is not stated in said phrase. The apparent word or phrase omission causes the excitation practice

to be vague and indefinite. Claims dependent from claim 173 directly or indirectly are also vague and indefinite due to their dependence. Clarification via clearer claim wording is requested. This rejection is necessitated by amendment.

#### PRIOR ART

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 128-130, 132, and 135-144 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Higuchi et al. [Bio/Technology 10:413(1992); already of record], taken in view of Haff et al. [Biotechniques, 10(1):102-112(1991)].

This rejection is reiterated and maintained for the above

listed claims from the office action, mailed 9/30/02. Applicants argue that neither of the references teach or suggest rapid cooling of the sample. In response the thin walls of the Haff et al. System 9600 was previously cited on page 106, first column, third full paragraph, as describing thin-walled tubes for conducting heat or for heat conduction. The instant claims cite means for rapid heating and cooling. The heat conduction means in Haff et al. is reasonably such means as heat conduction through thin-walled tubes is equally available in any direction, either into or out of a sample contained in such tubes and thus meets the "means" limitations in the claims for both heating and cooling means. It is noted that the instant claims are system claims and not method claims and therefore whether heating or cooling actually occurs is irrelevant on this issue as only the "means" are required in order to support the rejection on this issue. Applicants further argue that the means for positioning a sample container are not disclosed in either reference. In response both references describe the detection of fluorescence which must be positioned for such detection. Figure 3, part B, of Higuchi et al. clearly shows positions of sample during detection and Haff et al. describes a plate reader on page 103, second column, fifth full paragraph. Thus applicants' argument is contrary to the facts disclosed in either reference and therefore non-persuasive. Applicants further argue that the

combination of references does not describe monitoring "during" amplification because Haff et al. utilizes metal block encasement of the sample to result in rapid heating. In response Higuchi et al. in Figure 3 describes removal of the samples during amplification for positioning the samples for fluorescence detection at various numbers of cycles as shown in Figure 3, part B. This removal is thus also available with the Haff et al. disclosure and is not prevented by having the samples in a metal block also during amplification of various numbers of cycles between monitoring steps. In summary, the added temperature change rate limitations in various claims have resulted in removal of certain claims as being rejected on this basis, but that the above listed claims, which have not been amended to require the faster temperature change rates, remain properly rejected as previously set forth..

Claims 13-20, 23-25, 28-31, 128-132, 135-137, 140-143, 156-158, 160, 168-170, and 196 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Haff et al. (P/N 5,720,923).

This rejection is reiterated and maintained for the above listed claims from the office action, mailed 9/30/02, and as necessitated by amendment regarding newly added claim 196. It is noted that individual sample tubes in Haff et al. describe the individual samples as being detectably positioned within such tubes as required in instant claim 196. Applicants argue that

individual elements are not disclosed in Haff et al. as being interchangeable. Interchangeability is not an instant claim limitation and therefore this argument is moot in overcoming this rejection. Applicants then point to a rotating cylindrical drum that contains a heat exchanger assembly and admit of flexible capillary tubes as containing the sample which are described in citations as set forth in the previous office action as being means for temperature change of 8.75 degrees C. per second. Applicants allegation therefore that a drum/capillary tube system lacks the rapid temperature change limitation as in the above listed claims is contrary to the facts as set forth in the reference and therefore non-persuasive. Applicants then argue that means for positioning the sample in a monitoring position is lacking in the reference. In response the suggestion to utilize fluorescent detection for capillary tubes of various embodiments in the reference was pointed to in column 26, lines 13-57, and still is supportive of the rejection on this issue. Applicants have not persuasively argued what is not suggestive of such detection means other than an allegation which is clearly contrary to the factual basis for this rejection.

Claims 13-25, 28-31, 33-35, 55-59, 128-137, 140-143, 145, 146, 156-158, 160, 163-170, and 196 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Haff et al. (P/N 5,720,923); taken in view of Schregenberger (P/N 4,326,342).

This rejection is reiterated and maintained for the above listed claims from the office action, mailed 9/30/02, and as necessitated by amendment regarding newly added claim 196. It is noted that individual sample tubes in Haff et al. describe the individual samples as being detectably positioned within such tubes as required in instant claim 196. Applicants argue that there is no motivation or suggestion to combine Schregenberger et al. with Haff et al. In response such a motivation and suggestion was set forth in this rejection as previously set forth in the office action, mailed 9/30/02. Applicants have only alleged that there is no such motivation or suggestion but without supplying any factual basis to negate said previously set forth motivation and suggestion thus making their allegation without basis and thus non-persuasive.

Claims 13-35, 55-59, 79-82, 87-90, 118-125, 128-148, 151, 156-158, 160, 163-170, and 196 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Haff et al. (P/N 5,720,923); taken in view of Schregenberger (P/N 4,326,342), taken further in view of Jordan (P/N 4,325,910).

This rejection is reiterated and maintained for the above listed claims from the office action, mailed 9/30/02, and as necessitated by amendment regarding newly added claim 196. It is noted that individual sample tubes in Haff et al. describe the individual samples as being detectably positioned within such



tubes as required in instant claim 196. Applicants argue that there is no motivation or suggestion to combine Schregenberger et al., further in view of Jordan et al., with Haff et al. In response such a motivation and suggestion was set forth in this rejection as previously set forth in the office action, mailed 9/30/02. Applicants have only alleged that there is no such motivation or suggestion but without supplying any factual basis to negate said previously set forth motivation and suggestion thus making their allegation without basis and thus non-persuasive.

Claims 13-35, 55-59, 79-82, 87-92, 118-158, 160, 163-170, and 196 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Haff et al. (P/N 5,720,923); taken in view of Schregenberger (P/N 4,326,342), taken further in view of Jordan (P/N 4,325,910), taken further in view of Schembri (P/N 5,472,603).

This rejection is reiterated and maintained for the above listed claims from the office action, mailed 9/30/02, and as necessitated by amendment regarding newly added claim 196. It is noted that individual sample tubes in Haff et al. describe the individual samples as being detectably positioned within such tubes as required in instant claim 196. Applicants argue that there is no motivation or suggestion to combine Schregenberger et al., further in view of Jordan et al., further in view of

Schembri, with Haff et al. In response such a motivation and suggestion was set forth in this rejection as previously set forth in the office action, mailed 9/30/02. Applicants have only alleged that there is no such motivation or suggestion but without supplying any factual basis to negate said previously set forth motivation and suggestion thus making their allegation without basis and thus non-persuasive.

Claims 161, 162, 171, and 172 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 194 and 195 are allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with

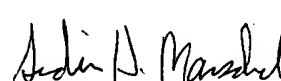
the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

June 9, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER